

## Seclusion and enforced medication in dealing with aggression

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**Seclusion and enforced medication in dealing with Aggression: a prospective dynamic cohort study**

## Abstract

*Background.* In the Netherlands, seclusion is historically the measure of first choice in dealing with aggressive incidents. In 2010, the Mediant Mental Health Trust in Eastern Netherlands introduced a policy prioritising the use of enforced medication to manage aggressive incidents over seclusion. The main goal of the study was to investigate whether prioritising enforced medication over seclusion leads to a change of aggressive incidents and coercive measures.

*Methods.* The study was carried out with data from 2764 patients admitted between 2007 and 2013 to the hospital locations of the Mediant Mental Health Trust in Eastern Netherlands, with a catchment area of 500000 inhabitants. Seclusion, restraint and enforced medications as well as other coercive measures were gathered systematically. Aggressive incidents were assessed with the SOAS-R. An event sequence analysis was performed, to assess whether seclusion, restraint or enforced medication were used or not before or after aggressive incidents.

*Results.* Enforced medication use went up by 363% from a very low baseline. There was a marked reduction of overall coercive measures by 44%. Seclusion hours went down by 62%. Aggression against staff was reduced by 40%.

*Conclusions.* When dealing with aggression, prioritising medication significantly reduces other coercive measures and aggression against staff, while within principles of subsidiarity, proportionality and expediency.

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Key words: Violence , emergency, quality of care, ethics and human rights.

## Introduction

The use of seclusion in dealing with aggression is increasingly perceived as an undesirable measure in dealing with aggression. From 2005 onwards the Dutch government spent more than 30 million euros in projects designed to reduce seclusion [1]. In several evaluations of Dutch mental health legislation and services [2-4] as well as in the opinion of policy makers [5] seclusion use was too abundant in dealing with aggression. In 2012 the Dutch government stated that any reduction of seclusion should not lead to substitution of seclusion by other measures [6]. At the same time studies showed that Dutch psychiatric patients do not have any particular preference for seclusion or enforced medication on average [7]. Recently, the UN special rapporteur on torture stated treatment against a patients consent in psychiatry may be seen as torture [8], adding to the controversy and leading to political discussions and changes of law over Europe.

In Dutch law, a doctor is required to evaluate the necessity of using coercive measures case by case and to carefully weigh the impact of measures taken against the background of three major principles: subsidiarity, proportionality and expediency [9]:

1. Subsidiarity: a more intrusive measure is only allowed when a lesser intrusive measure is insufficient to prevent danger;
2. Proportionality: the measure needs to be proportionate to the extent of the danger.  
The infringement on autonomy, and specifically the infringement of the bodily integrity of the patient, should not exceed the danger the patient may pose to others. The safety of the measure should be weighed against the risks to others if no action is taken. In the Netherlands, the psychiatrist must document which efforts were taken to ensure the patients' rights.
3. Expediency: the treatment or measure must have proven efficacy in dealing with the

danger the patient poses.

After introduction of the Dutch Mental Health Act in 1994 several evaluations proved a substantial increase in number and duration of seclusion time and incidents[2, 10]. Primarily due to the law prioritising the protection of a patient's bodily integrity over his or her mental integrity, the Mental Health Act led to seclusion becoming the measure of first choice in dealing with aggression in the Netherlands[11]. Nevertheless, no evidence underpins the therapeutic effect of seclusion [12]. The Dutch Mental Health Act provides a legal basis for admission but not treatment. In general, medication is offered to the patient, but commonly refused. During an admission, weeks can therefore pass without medication treatment despite clear symptomatology and a sometimes dormant danger level. Only Article 39 of the Dutch Mental Health Act allows short acting enforced medication in case of immediate danger. To deal with danger, seclusion was increasingly used in psychiatry[3, 10] and included up to 87% of all coercive measures in Dutch psychiatry. This had only reduced to 82% by 2013 [13]. Enforced medication covered approximately 12% of the measures [14, 15]. At the same time a substantial increase in involuntary admissions was observed [1]. Over the past few years, seclusion figures have reduced in line with international consensus in a minority of Dutch mental health institutes, however the major trends showed increasing differences of seclusion use amongst Dutch psychiatric hospitals [15]. Dutch national data show 75% of enforced medication is administered before, during or just after seclusion. Enforced medication is given in connection of only 20% of seclusion episodes, although the combination of seclusion with enforced medication nearly halves seclusion duration [14].

Mediant is a Mental Health Trust in the Eastern part of the Netherlands at the German border. It provides services for a population of around 500,000. It includes urban and rural areas. In 2010, Mediant changed their policy with regard to the use of coercive

measure from the use of seclusion as first choice in the management of aggression to a prioritization of enforced medication as coercive measure of first choice. With this policy, Mediant Mental Health Trust differed completely from other institutes in the Netherlands who continued to use seclusion as first choice and rare use of enforced medication [9, 14]. The policy was based on the principles of subsidiarity, proportionality and expediency, with an emphasis on providing evidence based treatments to patient. Whilst seclusion may reduce danger for the time being, it does not treat the cause of danger, which may include the psychiatric disorder of the patient. Enforced medication has some impact on the bodily integrity of the patient, but will often treat the underlying cause of danger. By starting with medication as coercive measure of first choice, seclusion may not be necessary or substantially shortened [14].

Both in the Netherlands and internationally, evidence is increasing showing interventions in dealing with aggression as seclusion, restraint or enforced medication vary largely between Mental Health Trusts [4, 14-18], and most certainly more than between countries [13]. In the Netherlands, such figures vary ten to twentyfold between hospitals, a difference that cannot be explained by variation in the severity of patients admitted [15]. In general, in the Netherlands, seclusion is used five times more often than enforced medication. Only a few Trusts follow international guidelines preferring enforced medication above seclusion, even though neither Dutch law nor Dutch guidelines prescribe a measure of first choice.

Ward policy in dealing with aggression may be supported by continuous assessment by means of the staff observation and aggression scale (SOAS-R) [19]. This instrument is internationally used to document aggressive incidents. It is used to assess both the nature and severity of aggression. Severe aggressive incidents have an important negative impact on

staff health and disrupt patient-staff interaction for some time.

No data exists with regard to the effect of a complete policy change in favour of enforced medication over seclusion. Our study examines the effect of the application of enforced medication as a measure of first choice on the number of aggression incidents as well as on the use of coercive measures.

## Methods

The current study describes seven year follow up data of a single Mental Health Trust. From 2007 onwards coercive measures have been documented by using the Argus scale [10], which comprehensively covers all coercive measures. Aggressive incidents were assessed by means of the SOAS-R. The policy change happened in 2010, near to a year after a change of hospital directors. patients. If a patient's presentation implied that medication would probably be inevitable, enforced medication was the measure of first choice. In unknown patients enforced antipsychotic medication continued to be given reluctantly. In these patients sedation without antipsychotic medication was the first choice. In known patients haloperidol became the medication of first choice, when necessary accompanied by promethazine or lorazepam [21]. The majority of patients treated at Mediant (above 80%) had relapsing episodes of mental illness and were well known to services.

*Setting.* The study was carried out across two hospital locations in the east of the Netherlands, with a total of 217 beds. 75 of these beds are admission ward beds, 62 beds are long stay and 80 are for specialized treatment such as non-congenital brain disorders and psychiatry for elderly adults.

*Argus dataset.* The Argus dataset covers coercive measures as counters and patient



background data as denominators [10 , 14]. For this study the database covered all available Argus data from this hospital from January 1<sup>st</sup> 2007 up till December 31<sup>st</sup>, 2013, leaving out admission days of patients admitted before or after these dates. The Argus coercive measures scale defines three main measures [10]:

1. Seclusion is defined as bringing the patient into a locked room where he/she is alone and able to move around. The patient is unable to leave due to a locked door.
2. Mechanical and manual restraint is defined as immobilizing the patient with external mechanical devices or physical force.
3. Enforced medication is defined as the application of intramuscular medication by force against the patient's will. In addition, medication administered under psychological pressure is registered, allowing comparisons with international data [18, 22-24].

Aggression was measured with SOAS-R [19]. The SOAS allows a differentiated view of the severity of aggression. The inter-observer reliability of the scale was found to be satisfactory (Nijman,, 1997) with a correlation between observers of 0.87 and a kappa of 0.61, indicating fair to good agreement (Lambert and Hill, 1991). The SOAS-R was completed about each incident when a member of staff was subjected to an aggressive incident. The use of SOAS-R as a monitoring instrument has been part of daily practice from 2006 onwards. We included all aggression incidents either with verbal or physical means used by the patient.

The current article primarily focuses on substituting one intervention with another, while controlling for patient's diagnosis and aggression. Despite the fact that politicians and policy makers point out that substitution of one coercive measure with another is not allowed [6], a clear definition is not provided. In the current article we

defined substitution in line with the international literature [12], as follows:

1. Substitution implies the replacement of one coercive measure with another.
2. To allow comparison of time in seclusion with time of medication efficacy, the number of days a patient was subjected to a coercive measure was counted. It was assumed that applying intramuscular haloperidol with or without a benzodiazepine remains active in the patient for three days. This is a deliberately generous interpretation of the half-life of the medication in order to avoid accusations of trying to minimise its effect. In the case of depot medication (seldom used against a patient's will) the efficacy was set at three weeks.

*Patient background data.* The database covered patient characteristics such as gender, date of birth, marital status, ethnicity, diagnosis (ICD-10) and Global Assessment of Functioning (GAF) scores allowing international comparisons.

*Design and statistical analysis.* This study is a longitudinal dynamic cohort study comparing findings to nationwide data. Two exposure periods were defined, before and after the policy change in 2010. Firstly, to obtain an impression of the population, the exposure to aggression, seclusion and enforced medication was calculated over the first three years (2007-2009) and over the last three years (2011-2013). For this analysis we aggregated admissions to a patient level. In this stratified database, patients admitted in both timeframes occurred twice. Furthermore, we constructed a database at a day to day intervention level. Patient characteristics were identified in both databases but the wards where interventions occurred only in the intervention level database.

In the analysis the number of started seclusions and aggression incidents were used as counters together with time spent in seclusion. Admission time and the population

number of the catchment area were used as denominators. In the same way time in seclusion or the numbers of days having been subjected to medication were used as counters whilst admission time of a patient in a year was used as numerators. These figures were compared with nationwide figures calculated in the same way.

Events sequences were counted by looking to moments in time when aggression occurred or decisions to seclude or administer enforced medication were made. The sequences of one measure following another were counted, over a number of categories. Differences between years were tested by means of chi-square or student-test when appropriate. A full listing of all variables and underlying calculations is presented in table 1.

Table 1 about here

Possible confounding factors by patient or ward characteristics were investigated in three ways, correcting for patient characteristics before and after policy change. We performed a logistic regression on seclusion and a linear regression on the log of seclusion time per admission time on the patient level database. In the intervention level database we performed a mixed models repeated measures analysis, nested by ward, on seclusion duration. In all these analyses admission duration was included as an exposure variable. Findings of these analyses are reported only within the context of case mix correction.

An analysis of variance was performed to identify possible differences or similarities in trends between the Trust and the nationwide databases. As the nationwide databases were received anonymously, and patients could not be followed over years for that comparison case mix correction was not feasible.

**Results**

Table 2 describes the patient population at risk of coercive measures throughout the years examined. The table shows some substantial differences before and after the policy change, within the total population and within specific patient groups. The percentage of patients or staff subjected to aggression, seclusion or enforced medication all decreased by 27 - 45%. In F2 (schizophrenia, schizotypal and delusional disorder) and F6 (Personality disorders) the most changes were seen, with the number of patients being aggressive, the number of patients secluded and the number of patients receiving enforced medication all substantially reducing after the policy change in 2010.

Table 2 about here

Table 2 compared the several coercive measures to the number of admissions and admission time. The main finding was a clear decrease in seclusion time over the years examined (-62%) was accompanied by a clear increase (+363%) of days being subjected to enforced medication. However, importantly, the number of days patients were subjected to any type of coercion per 1,000 admission days reduced by 43%. Looking at the number of aggression incidents we observed a reduction of 40%. Putting these data into a nationwide Dutch perspective, the seclusion hours per 1,000 admission hours were clearly above the nationwide figure at Mediant before the policy change. After the policy change the coercion data were clearly below nationwide average data.

An analysis of variance on the aggregated figures presented in table 2 showed no significant differences between the investigated Trust and nationwide trends of medication events per admission days and seclusion hours per admission hours. The trends on

seclusions per inhabitants did show a significantly steeper decrease in the nationwide data ( $f=6.46$ ;  $p=0.04$ ). However, the investigated Trust started lower and ended lower.

The multivariate logistic regression analysis showed that policy (OR before-after: 0,51,  $p<0.000$ ), more admission days (1,02,  $p<0.000$ ), male gender (OR 1,51,  $p<0.000$ ), young age (OR=1.31,  $p=0.090$ ), having no partner (OR=1,41;  $p=0.007$ ), ethnic origin (OR=1,65,  $p=0.004$ ), neurotic disorders (OR=0,427,  $p<0.001$ ), psychotic disorder (OR=2.02,  $p<0.000$ ), and organic disorders (OR=1,54,  $p=0.025$ ) were associated with an increased chance of being secluded. The linear regression revealed similar variables to be associated with seclusion hours per admission hours, namely the policy change (standardized  $\beta=-0.112$ ;  $p=0.006$ ), no partner (standardized  $\beta=0.097$ ;  $p=0.019$ ), psychotic disorder (standardized  $\beta=0.225$ ;  $p=0.002$ ), mood disorder (standardized  $\beta=0.131$ ;  $p=0.031$ ), personality disorder (standardized  $\beta=-0.145$ ;  $p=0.026$ ), organic disorder (standardized  $\beta=-0.112$ ;  $p=0.012$ ), and the number of admission days (standardized  $\beta=0.403$ ;  $p<0.000$ ). As table 1 shows, most of these variables are consistently distributed before and after the policy change. Two variables occur differently in the before and after sample: After the policy change there were more patients diagnosed with substance misuse disorders and less with personality disorders. However, substance misuse disorder occurred in a low number of patients, whereas personality disorder was inversely associated with the logarithm of hours in seclusion per admission hours. The multilevel analysis confirmed these findings with inverse associations of the policy change (OR=0.41,  $p<0.001$ ), neurotic disorder (OR=0.58,  $p=0.001$ ) and personality disorder (0.38,  $p<0.001$ ) to seclusion duration at an intervention level and positive associations of miscellaneous disorders (unknown patients; OR=7.69,  $p<0.001$ ), substance abuse (OR=10  $p<0.001$ ), and psychosis (OR=4.34,  $p<0.001$ ). Medication and aggression were not included in the regression analyses due to

collinearity.

Table 3 about here

Looking at the number of times in which measures were started and aggressive incidents were followed or preceded either by seclusion or enforced medication incidents, we observed some striking changes: Before the policy change 645 incidents of seclusion occurred without any other measure. After the policy change this went down to 427. Seclusion as the first measure remained stable at 31 and 32 events respectively. Medication was first given in combination with seclusion in 112 events before the policy change and 43 after. Most importantly, medication as the only coercive measure went up from 20 before to 193 events after the policy change. All measures also reduced from 1044 to 818. The number of aggression incidents occurring in direct relation to coercion reduced from 228 to 135 over the three examined years before and after the policy change respectively. Aggression incidents without a coercive response reduced from 1342 to 822 incidents.

## Discussion

Our data suggests that prioritising enforced medication over seclusion as first choice strategy to manage aggression is feasible. After the policy change almost 37% of coercive measures were medication in contrast to around 13% in the rest of the Netherlands. From a Dutch perspective involuntary medication use in the investigated Trust was high. With 9% of all admitted patients subjected to involuntary medication, it was nearly four times as high as expected, considering the Dutch nationwide data. This is comparable with Norwegian, Danish and English data, although with a prevalence of 2.6% of all admitted patients being

subjected to involuntary medication (Noorthoorn et al, 2015), the Netherlands are at the lower end of European data for coercive medication use. The Dutch data compares favourably to German findings, where an involuntary medication exposure prevalence of 1.6% was reported (Flammer et al 2013). However, overall prevalence of exposure to *any* involuntary coercive measure during a psychiatric admission is very similar in Wales, Ireland and Germany with around 5.5%, but higher in the Netherlands with 9.4% (Lepping et al, 2016).

The data showed that prioritising medication over seclusion led to the expected increase in the use of medication but also a significant reduction in seclusion times and incidents as well as a reduction of aggression on staff. Concerns by nurses that using less seclusion may be more risky for the ward environment were not substantiated by our data. The findings show that a conscious decision to start medication treatment without delay can lead to important shifts in ratio figures lessening the need for seclusion whilst also reducing the total amount of coercion. The total coercive incidents diminished by more than half, when we look at change over time. This study additionally shows a secondary reduction in the number of aggression incidents following the policy change. Starting prompt treatment not only reduces seclusion incidents, but also overall seclusion times.

Two studies have examined preferences for coercive measures amongst the Dutch patient population [6, 10]. 50% of the patients surveyed preferred enforced medication over seclusion with the other 50% preferring seclusion. In a more recent clinical trial Georgieva et al. [24] showed that when medication is used as a measure of first choice, seclusion duration reduced by up to 75%. This was despite the fact that the number of times enforced medication was given did not differ between experimental and control wards in that study.

However, the experimental wards had significantly shorter average lengths of stay. This shows that medication use can have an effect on seclusion incidents and times, aggression and length of stay.

In Mediant the findings of the above studies were implemented in daily practice. When choosing coercive measures, the risks of enforced medication were balanced with the danger caused by the patient. Many patients were well known and had signed advanced directives in their medical charts allowing the use of enforced medication which were further encouraged. In the current study, not only duration, but also the number of incidents decreased. However, findings are difficult to compare, as the current study is an evaluation of treatment policy, supported by the medical director and team management. In contrast, the study by Georgieva is a clinical trial where teams were asked to comply with a study protocol with an experimental and a control ward.

**Commented [P1]:** Needs reference

The findings of this study show that a policy to use enforced medication as a measure of first choice in dealing with aggression not only leads to lower seclusion figures in a Dutch perspective, but also to fewer aggressive incidents and fewer total coercive measures. We argue that this is because the disorder of the patient is dealt with at an early stage of the admission. Of course, treating patients without coercion will always be preferable. Therefore, advanced directives and early risk assessment may support further reductions in the use of coercive measures.

A strength of the study is that we used the complete data of an entire mental health provider for a large area over a substantial number of years and a substantial number of patients. The policy change which is the focus of this study occurred in the middle year of our data collection, allowing to investigate the effect of this policy change, not only on seclusion findings, but also against the background of all coercive measures and admission



data. At the same time the use of data of a single hospital is a limitation of the study. Other not measured organisational changes, such as implementation of the engagement model, working with experience workers, variations in personnel and slight changes of the environment could have had an effect. Variation in patient case mix was only controlled for in the hospitals' sample, but not in the nationwide data. Also, it cannot be ruled out that single patients who were repeatedly coerced may have had a small effect on the final data.

Both Dutch [25, 26] and international studies [24, 27, 28] support choices made in this hospital. In order to implement such a policy change, support at a central level within an organisation is essential. It is important to ensure all professionals comply with the policy.

## **Conclusion**

Prioritising enforced medication over seclusion as first line treatment for the management of aggression can reduce seclusion incidents and times as well as aggression, whilst operating within the principles of subsidiarity, proportionality and expediency.

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**Compliance with ethical standards.**

**Conflict of interest.** The authors declared no conflict of interest.

**Ethical approval.** All procedures performed in the current study were in accordance with the ethical standards of the National Research committee as obtained in 2006 and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Data were analysed on fully anonymised data of which none of the cases could be identified to an individual.

**Table 1** Patient compilation, aggression incidence, seclusion and enforced medication before and after policy change

Patient characteristics	Before policy change				After policy change				Significant Difference*		
	sample	aggression	seclusion	medication	sample	aggression	seclusion	medication	aggression	seclusion	medication
Young	487 (35%)	9%	9%	4%	731 (40%)	6%	6%	3%		0.001	0.000
Male patient	660 (47%)	11%	12%	4%	919 (50%)	6%	8%	3%	0.000	0.000	
No partner	939 (67%)	12%	10%	4%	1312 (71%)	12%	10%	4%	0.031	0.000	0.000
Non-western descent	102 (7.3%)	2.1%	2.2%	1%	118 (6.4%)	1.6%	1.5%	1%	0.004	0.000	
No ICD – 10 diagnosis	43 (3%)	14%	9%	2%	66 (3.6%)	15%	11%	4%			
F0 Organic disorders	110 (8%)	38%	19%	4%	189 (10.3%)	23%	12%	2%	0.005		
F1 Disorders due to psychoactive substances	34 (2%)	14%	15%		91 (5%)	13%	9%	2%			
F2 Schizophrenia, schizotypal & delusional disorders	362 (26%)	30%	32%	17%	552 (30.1%)	22%	20%	11%	0.004	0.000	0.006
F3 Mood disorders	160 (11.5%)	15%	27%	15%	340 (18.5%)	12%	11%	5%		0.000	0.000
F4 Neurotic, disorders	101 (7.3%)	13%	9%	5%	92 (5%)	4%	2%				
F6 Personality disorders	507 (36.4%)	22%	16%	5%	429 (23.4%)	10%	8%	3%	0.000	0.000	
Below 40 GAF score	1392	38%	35%	29%	1836	28%	28%	11%			
All patients	1392	23%	22%	9%	1836	16%	13%	5%	0.000	0.000	0.000

\* differences tested by means of chi square between the same item before and after.

**Table 2 Seclusion and enforced medication compared to admissions and admission time**

	Before policy change			Implement ation year	After policy change			
Counters and denominators								%Δ
Medaint 2007-2013	2007	2008	2009	2010	2011	2012	2013	Before and after
Aggression incidents as measured with the SOAS-R	488	361	721	496	319	349	289	-40%
Started seclusions*	383	301	282	281	219	364	193	-50%
Patients admitted*	740	737	767	639	853	918	926	+20%
Seclusions per 100 admissions per year**	52	41	37	44	26	39	21	-59%
Seclusion days**	2131	1709	1124	901	855	356	711	-62%
Seclusion hours**	54972	50183	36640	44435	25117	16259	12811	-62%
Patients secluded*	128	114	110	91	108	102	89	-16%
% patients exposed	17.2%	15.4%	14.3%	14.2%	12.6%	11.1%	9.6%	-55%
Days enforced medication / 100000 admission days	69	67	112	163	301	469	320	+363%
Days coercion**	2194	1771	1228	1064	1156	752	1008	-44%
Patients with enforced medication	48	59	57	59	49	45	39	-20%
Admission days	91074	93030	93251	100047	100093	84397	92877	+1%
Hours seclusion per 1000 admission hours**	25	22	16	19	10	8	6	-62%
Days coercion per 1000 admission days**	24	19	13	11	12	9	11	-43%
Catchment area	392000	394200	398100	402100	405300	408100	409460	+4%
Seclusions per 100000 inhabitants	0.97	0.76	0.70	0.69	0.54	0.89	0.47	-48%
Nationwide data 2007 - 2013								
N admissions	9057	11130	21500	26686	42960	113290	100228	
% patients exposed	12.1	11.8	10.8	10.2	8.7	6.5	7.0	-40%
Hours seclusion per 1000 admission hours	12.3	11.2	10.5	11.6	9.7	8.6	9.1	-25%
Days enforced medication / 100000 admission days	57	72	99	105	135	138	243	+426%
Number of seclusions	3186	3685	4750	5525	7476	9469	9802	
Catchment area	242800	253500	362400	4563000	760500	168584	169751	
Seclusions per 100000 inhabitants	1.31	1.45	1.31	1.21	0.98	0.56	0.57	- 57%
Event sequences 2007-2013***								
Seclusion only**	300	209	136	200	131	109	187	-36%
Aggression preceded seclusion only**	58	23	17	11	28	9	29	-33%
Seclusion followed by medication decisions*	6	7	13	48	11	6	15	+23%
Medication decisions followed by seclusion**	29	32	51	23	25	5	13	-62%
Aggression & med. followed by seclusion	4	7	10	4	4	3	3	-53%
Medication only decisions**	6	5	9	38	17	118	58	+865%
Seclusion only followed by aggression**	25	22	45	4	9	3	11	-75%
Aggression followed by seclusion	62	30	27	15	32	12	32	-36%

\*P<0,05 \*\*P<0,001 \*\*\*Combinations of events occurring more than 20 times per 3 years are presented.

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